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*To ensure access to high-quality,
patient-centered, cost-effective
health care to Los Angeles County
residents through direct services at
DHS facilities and through
collaboration with community and
university partners.*



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May 17, 2016

The Honorable Board of Supervisors
County of Los Angeles
383 Kenneth Hahn Hall of Administration
500 West Temple Street
Los Angeles, California 90012

Dear Supervisors:

**REQUEST APPROVAL TO EXECUTE A NO-COST CLOSED DOOR
CERTIFICATION WITH GENENTECH, INC. AND FUTURE
PHARMACEUTICAL MANUFACTURERS FOR ACCESS TO SPECIALTY
PHARMACEUTICALS
(ALL SUPERVISORIAL DISTRICTS)
(3 VOTES)**

SUBJECT

Request approval to execute a no-cost Closed Door Certification with Genentech, Inc., which includes a provision for indemnification and delegated authority to execute future agreements with various pharmaceutical companies to access their specialty pharmaceuticals.

IT IS RECOMMENDED THAT THE BOARD:

1. Authorize the Director of Health Services (Director), or his designee, to sign a Closed Door Certification (CDC), which includes a provision for indemnification, with Genentech Inc. (Genentech), to continue access to purchasing their specialty pharmaceuticals, effective on Board approval.
2. Delegate authority to the Director, or his designee, to execute future agreements with various pharmaceutical manufacturers, who provide limited distribution pharmaceuticals to the Department of Health Services (DHS), which may include provisions for indemnification, subject to review and approval by County Counsel and the Chief Executive Office's (CEO's) Risk Management Division.

ADOPTED

BOARD OF SUPERVISORS
COUNTY OF LOS ANGELES

21 May 17, 2016

LORI GLASGOW
EXECUTIVE OFFICER

PURPOSE/JUSTIFICATION OF RECOMMENDED ACTION

Several pharmaceutical manufacturers, including Genentech, are in the process of taking steps to limit distribution of their pharmaceuticals through a specialty distribution network to increase their control, which allows them to track use of their products more closely. The limited distribution model is for patient safety, to protect the integrity of the pharmaceuticals as they move through the supply chain, and to ensure patients and healthcare providers are able to access pharmaceuticals. Genentech provides DHS with mostly oncology medications through a specialty distribution network. These pharmaceuticals are procured through Cardinal Health, DHS' primary pharmaceutical distributor. In order to continue having access to Genentech's pharmaceuticals, Genentech is requiring DHS to sign their CDC (Exhibit I), to certify their pharmaceuticals are being dispensed at DHS on-site pharmacies to DHS patients only, and not being resold to non-DHS pharmacies. DHS-procured pharmaceuticals are only provided to patients serviced at a DHS facility and assigned a medical record number by DHS. The CDC includes an indemnification provision that requires DHS to indemnify and defend Genentech from and against any liability, claim, loss, damage or expense incurred by Genentech, including without limitation, reasonable attorneys' fees, arising from DHS' negligent acts or omissions in connection with DHS' performance or breach of the CDC. Genentech has not been willing to waive this requirement. Without access to Genentech's pharmaceuticals at DHS pharmacies, patients will have to obtain their medications from non-DHS specialty pharmacies.

Approval of the first recommendation will authorize the Director, or his designee, to execute a CDC with Genentech, that includes a provision for indemnification, that will allow DHS access to purchasing Genentech pharmaceuticals for patients serviced at DHS facilities and pharmacies, effective on Board approval.

Approval of the second recommendation will allow DHS to execute future agreements, which may include provisions for indemnification, with various pharmaceutical manufacturers who provide limited distribution pharmaceuticals to DHS, subject to review and approval by County Counsel and CEO's Risk Management Division.

Implementation of Strategic Plan Goals

The recommended actions support Goal 1, Operational Effectiveness/Fiscal Sustainability of the County's Strategic Plan.

FISCAL IMPACT/FINANCING

The CDC has no fiscal impact on DHS' budget.

FACTS AND PROVISIONS/LEGAL REQUIREMENTS

DHS pharmacies procure pharmaceuticals through their pharmaceutical distribution agreement with Cardinal Health. DHS does not have a direct agreement with Genentech, but since DHS is the end-user of their products, Genentech reserves the right to cease access of their medications to DHS via Cardinal Health, unless DHS signs the CDC.

County Counsel has approved Exhibit I as to form. CEO's Risk Management Division has reviewed and approved the indemnification provision in Exhibit I.

CONTRACTING PROCESS

Not applicable.

IMPACT ON CURRENT SERVICES (OR PROJECTS)

Approval of the recommendations will ensure DHS continues to have access receiving and dispensing Genentech pharmaceuticals to DHS serviced patients. If DHS does not sign the CDC, Genentech will cease providing access of their pharmaceuticals to DHS through Cardinal Health and patients will be directed to outside non-DHS specialty pharmacies for their medications that are manufactured by Genentech.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Mitchell Katz". The signature is fluid and cursive, with the first name "Mitchell" written in a larger, more prominent script than the last name "Katz".

Mitchell H. Katz, M.D.

Director

MHK:sa

Enclosures

c: Chief Executive Office
County Counsel
Executive Office, Board of Supervisors

CLOSED DOOR CERTIFICATION

This Closed Door Certification sets forth the obligations of the Participant(s) (as defined below), with respect to the purchase of Genentech products.

I, _____ **[Insert Name]**, hereby certify that I am the
 _____ **[Insert position and title]** of
Los Angeles County Department of Health Services and that I am duly qualified and authorized to sign
 this Certification on behalf of the Participant(s)
 (as defined below). I hereby represent and certify as follows:

1. The information provided herein is true and correct;
2. The "Participant(s)" shall mean those facilities listed in Exhibit A to this Certification and shall mean health care provider(s) that dispense pharmaceutical products and ensure safe and effective medication use for their own operations. Participants shall not include any free-standing retail pharmacy facilities;
3. Participant is (i) a State entity that operates a physician practice group with a scope of services that cover an exclusively out-patient oncology center or medical oncology office where licensed physicians provide patient care and services, or (ii) a licensed hospital or medical center as recognized by the American Hospital Association and any other sources that Genentech may use to identify acute care facilities, that provides inpatient services (diagnostic and/or therapeutic) for a variety of medical conditions, both surgical and non-surgical, or (iii) a political subdivision of the State of California that operates a municipal health system that includes acute care hospitals providing inpatient services for a variety of medical conditions.
4. The product(s) purchased by the Participant are only for dispensing to its patients in connection with the provision of treatment and/or evaluation, and not for resale to any wholesaler, retailer, internet pharmacy, institution, physician or any other person or entity, within or outside of the U.S. Participant shall maintain records of its product purchases and the circumstances of dispensing same to adequately reflect its compliance with the terms of this provision;
5. If Participant fails to observe the terms of this Certification, Genentech may cease providing access to product(s) made available to Participant, and Genentech may at its option, take other action that Genentech deems appropriate; and
6. Participant acknowledges and agrees that it shall be responsible for any liability, claim, loss, damage or expenses incurred by Genentech, including without limitation, reasonable attorneys' fees, arising from its negligent acts or omissions in connection with its performance of its obligations stated herein, or its breach of this Certification, as determined by a court of competent jurisdiction and the Participant's liability is governed by the terms of the State of California.

IN WITNESS WHEREOF, the undersigned has executed and delivered this Certification as of the date set forth below.

Signature: _____ Title: _____

Print Name: _____ Date: _____

Please send this "Closed Door Certification" via:

Email to: MCCLOA@gene.com

eFax to: (877) 917-4950

Mail to: Genentech USA, Inc., Attention: Managed Care Contracts
 1 DNA Way, Mailstop, South San Francisco, CA 94080

EXHIBIT A

Parent Organization: _____

Parent Class of Trade/Type of Provider: _____

Parent HIN: _____

PARTICIPANTS

Participant Name: _____

Address: _____

City, State, Zip Code: _____

Class of Trade/Type of Provider: _____

HIN: _____

DEA: _____

Primary Authorized Wholesaler: _____

Participant Name: _____

Address: _____

City, State, Zip Code: _____

Class of Trade/Type of Provider: _____

HIN: _____

DEA: _____

Primary Authorized Wholesaler: _____

Participant Name: _____

Address: _____

City, State, Zip Code: _____

Class of Trade/Type of Provider: _____

HIN: _____

DEA: _____

Primary Authorized Wholesaler: _____